QUALITY CONTROL MATERIALS FOR GENETIC TESTING CONFERENCE
SEPT. 15-16, 2003, ATLANTA, GA

Overview

The **Quality Control Materials for Genetic Testing** conference, organized by the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the National Institutes for Standards and Technology (NIST), was held on Sept. 15-16, 2003, at the Sheraton Colony Square Hotel in Atlanta, GA. Participants of the conference included more than 50 leaders in genomics from professional organizations, government agencies, industry, laboratories, and academic institutions. The main goals of the conference included: 1) To review the current and future needs for quality control (QC) materials for genetic tests; 2) To describe the efforts to produce materials suitable for positive QC for genetic tests; and 3) To develop sustainable, practical means to provide QC materials to genetic testing laboratories at a reasonable cost.

The meeting began with an introduction and welcoming remarks by Dr. D. Joe Boone, Associate Director for Science, Division of Laboratory Systems, Public Health Practice Program Office, CDC. Dr. Lawrence M. Silverman, Professor of Pathology at the University of Virginia, gave an overview on guidelines, oversight, availability, and challenges for QC materials for genetic tests. During the meeting, a number of efforts to develop and provide QC materials for genetic tests and testing in other areas were presented, including two CDC-funded projects to develop positive QC materials for molecular genetic testing, efforts to generate synthetic DNA constructs or sequences containing multiple mutations for use as control materials for cystic fibrosis (CF) and other disease testing, development of cDNA internal standards for gene expression analysis, use of dried blood spots in proficiency testing (PT) and quality assurance (QA) for newborn screening programs and European projects to develop and provide QC materials for genetic testing.

The meeting included three panel discussion sessions on applicability of existing efforts to current and future needs for QC materials, practical issues related to collection, validation, and provision of QC materials, and mechanisms needed for bridging the gaps and sustaining the process. Issues that participants discussed included areas of need for QC materials at present and in the future; strengths and weaknesses of current efforts; impact of patents and licensing agreements on development and distribution of QC materials; mechanisms for development, collection and storage, validation, and distribution of QC materials; provision of materials needed for tests for rare diseases; cost considerations for obtaining validated QC materials, and models and mechanisms for sustaining the process.

At the conclusion of the meeting, participants identified eight areas of needs, including 1) Raise awareness about research activities on developing QC materials and facilitate collaboration among research efforts; 2) Develop better coordination of funding sources and opportunities; 3) Develop professional guidance on appropriate QC practices; 4) Clarify regulatory requirements for providers of QC materials; 5) Develop validation processes for QC materials; 6) Develop processes to use existing cell banks as sources for QC materials; 7) Develop a scheme to set priorities for QC materials; and 8) Develop networks of contributors of QC materials. In light of

the broad scope of these issues, a total of eight workgroups were assigned to address each identified need. The next meeting was proposed for March 8, 2004 in Orlando, Florida, to review workgroup progress and develop future directions.